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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,186	07/13/2001	Mary Jeanne Kreek	600-1-284N	3062

23565 7590 03/25/2003

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EXAMINER	
SAKELARIS, SALLY A	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,186	KREEK ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *31-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 31-47, drawn to a variant allele of a human orphanin FQ/nociceptin receptor gene, cloning vector, expression vector, and unicellular host, kit containing primers and to nucleic acids as classified in class 435, subclass 6, 69.1, 252.3 and 320.1 and Class 536, subclass 23.1, 23.5, 24.31 and 24.33.

II. Claims 48-58, drawn to a method for determining a susceptibility to an addictive disease or pain, or to determine a therapeutically effective amount of a therapeutic agent by genotyping as classified in class 435, subclasses 6 and 91.2.

1. The inventions are distinct, each from the other because of the following reasons:

a. Inventions I and II are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of invention I can be used in a materially different process such as for creating a haplotype for the human orphanin FQ/nociceptin receptor gene.

Sequence Election Requirement Applicable to All Groups:

2. Each gene sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the nucleotide that characterizes each gene differs in

structure and as a result also in function and in biological activity. A restriction is applied to each Group. For an elected Group drawn to a variant allele of a human orphanin FQ/nociceptin receptor gene, cloning vector, expression vector, and unicellular host, kit containing primers and to nucleic acids (Group I) or a method involving the use of a variant allele of a human orphanin FQ/nociceptin receptor gene, cloning vector, expression vector, and unicellular host, kit containing primers and to nucleic acids (Group II), a single SEQ ID NO: and a single variation found in that single SEQ ID NO: 1 must be further elected. Furthermore if Group I, including in part a kit invention, is elected, applicant must further elect a single pair of primers to amplify the elected single nucleotide residue (See MPEP 803.04).

For example, if applicant elects group I, they must then further elect a **single** nucleotide variation from the 9(G-46A, GIVS I 135C, GIVS I 205A, GIVS I 251A, C510T, CIVS III 67T, A804G, C1026T, C1126G) they have disclosed of the human orphanin FQ/nociceptin receptor gene and the **single** pair of primers suitable for this variant's amplification to comprise the kit. The same holds true if applicant would elect group II, the method concerning the human orphanin FQ/nociceptin receptor gene for determining susceptibility and therapeutically effective amounts, as they would be required to further elect a **single** allele of the human orphanin FQ/nociceptin receptor gene to practice their methods of determining susceptibility and determining a therapeutically effective amount of pain reliever necessary to treat a **single** addictive disease.

Another example would be if Group II was elected, then the variation, **G-46A** could be chosen for the determination of **opioid** addiction.

Additionally, Group I's election could also include the further election of a nucleic acid comprising an intron of the human orphanin FQ/nociceptin receptor gene as set forth in SEQ ID NO:2.

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences with different compositions are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

3. Applicant is advised that examination will be restricted to only the elected nucleotide variants of elected SEQ ID NOS: and methods involving these sequences or kit components and should not be construed as a species election.

4. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

3/20/03

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
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